Great Ships Initiative

GREAT SHIPS INITIATIVE (GSI)

TECHNICAL SYSTEMS AUDIT CHECKLIST FOR SAMPLES COLLECTED DURING DISCHARGE

Purpose/Scope of Audit:	**GSI Research, Development, Testing, and Evaluation (RDTE) Facility Technical Systems Audit**
Brief Description of Audit:	Audit of sample labeling, collection, transport, and analysis at the GSI RDTE Facility during performance evaluation of the Siemens SiCURE Ballast Water Management System.
Auditee:	GSI scientists
Audit Location:	RDTE Facility (Superior, WI)
Auditors:	Kelsey R. Prihoda, GSI Assistant Quality Assurance Manager
Audit Dates:	Monday, August 31, 2009

SAMPLE BOTTLE LABELING, SAMPLE COLLECTION, AND SAMPLE TRANSPORT TO UWS

SAMPLE TEST ID: 09-SI-1D

Relevant GSI SOPs:

- *GSI/SOP/G/RA/SC/3 – Procedure for Labeling Samples Collected at the GSI Land-Based RDTE Facility*
- *GSI/SOP/LB/G/O/5 – Procedure for Injecting Organisms and Solids into the GSI Land-Based RDTE Facility*
- *GSI/SOP/LB/RA/SC/3 – Procedure for Algae/Small Protozoa Sample Collection*
- *GSI/SOP/LB/RA/SC/4 – Procedure for Microbial Sample Collection*
- *GSI/SOP/LB/RA/SC/6 – Procedure for Zooplankton Sample Collection*
- *GSI/SOP/LB/RA/SC/3 – Procedure for Collecting Physical/Chemical Data and Samples at the GSI Land-Based RDTE Facility*

Sample Collection Type (Code)	Sample Port/Point	Tub Number	Sample Type (Collected By)	Labeled Correctly & In Crate?		Collected Following SOPs?		Transported Back to UWS?	
				Y	N	Y	N	Y	N
Control Tub (C)	SP9-C	1	Phytoplankton	✓		✓ 10:43			
			Zooplankton	✓		✓ 10:40			
			Microbe Rep. 1	✓		✓ 10:43			
			Microbe Rep. 2	✓		✓ 10:43			
			Microbe Rep. 3	✓		✓ 10:44			
			TRC and TRO	✓		✓ 10:44			
			Disinfection Byproducts (2 L)	✓		✓ 10:44			

→ yes ✓

✓

→ yes

Initial/Date

KRP/10-2-09

Sample Collection Type (Code)	Sample Port/Point	Tub Number	Sample Type (Collected By)	Labeled Correctly & In Crate? Y	Labeled Correctly & In Crate? N	Collected Following SOPs? Y	Collected Following SOPs? N	Transported Back to UWS? Y	Transported Back to UWS? N
control ~~Pre-Treatment~~ (2) In-Line (~~PT~~) C	SP10-C		TSS Rep. 1 10 min. after discharge	✓		✓ 9:46		✓ Heidi Saillard	
			TSS Rep. 2 30 min. after discharge	✓		✓ 10:06		✓	
			TSS Rep. 3 50 min. after discharge	✓		✓ 10:26		✓	
Treatment Tub #4 (T)	SP9-C	4	Phytoplankton	✓		✓			
			Zooplankton	✓		✓ To be archived			
			Microbe	✓		✓		✓ Heidi Saillard	
			+ DUP TRC and TRO	✓		✓			
Treatment Tub #5 (T)	SP9-B	5	Phytoplankton	✓		✓			
			Zooplankton	✓		✓ To be analyzed			
			Microbe	✓		✓		✓ Heidi Saillard	
			TRC and TRO	✓		✓			
Treatment Tube #6 (T)	SP9-A	6	Phytoplankton	✓		✓			
			Microbe	✓		✓		✓ Heidi Saillard	
			TRC and TRO	✓		✓			
			Whole Effluent (~38 L)	✓		✓		✓ Christine Polking-horne	
			Disinfection Byproducts (2 L)	✓		✓		✓ Heidi Saillard	
Treatment In-Line (T)	(3) ~~SP10-C~~ THP *		(1) TSS, ~~POC, DOC~~ Rep. 1 – ~10 min.	✓		(3) 11:54 ~~11:44~~ not collected		✓ Heidi Saillard to transport	
			TSS, ~~POC, DOC~~ Rep. 2 – ~30 min.	✓		12:00		✓	
			TSS, ~~POC, DOC~~ Rep. 3 – ~50 min.	✓		12:20		✓	
			TSS, ~~POC, DOC~~ Rep. 3 - ~50 min. Duplicate	✓		✓ 12:20		✓	
Treatment Tank 2	Mid-Depth		TRC Monitoring – Day 4	✓		✓ 11:58			

(1) TSS will be measured for water quality not POC or DOC.

(2) R.E. KMP 8-31-09

(3) TSS will be collected from a tap off of the treatment line rather than SP10-C due to recirculation of T1 into C1 on "discharge" of T1. This sampling location does not have a pitot therefore, it may not be a valid location to collect TSS samples. KMP/10-2-09

Initial/Date

SAMPLE ANALYSIS

SAMPLE TEST ID: 09-SI-1D

QUALITY SYSTEM DOCUMENTATION

AUDIT QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
1. Is there an approved Quality Assurance Project Plan for the overall project and has it been reviewed by all appropriate personnel?		✓		
2. Is a copy of the current approved QA Project Plan maintained near laboratory work station areas?			✓	
3. Is the implementation of the project in accordance with the QA Project Plan?				
4. Are there deviations from the QA Project Plan? Explain.				
5. Do any deviations from the QA Project Plan affect data quality?				
6. Are sample handling and storage procedures in accordance with the QA Project Plan?				
7. Are written and approved current standard operating procedures (SOPs) used in the project? If so, list them and note whether they are maintained near laboratory work station areas?				
8. Are data/observations appropriately recorded in laboratory notebooks/forms according to the QA Project Plan (i.e., entries in ink, dated, initialed, corrections done properly)? Are data contained in bound, well-labeled notebooks or three-ring binders?				
9. Do supervisory and/or QA personnel inspect laboratory notebooks/forms on a regular basis and initial notebook after review?				
10. Are paper records written in indelible ink?				
Additional Questions or Comments:				

Initial/Date

KMP/10-26-09

CHEMISTRY

Relevant GSI SOPs:

- *GSI/SOP/BS/RA/C/2 – Procedure for Determining Total Residual Oxidants (TRO) in Water*
- *GSI/SOP/BS/RA/C/3 – Procedures for Measuring Organic Carbon in Aqueous Samples*
- *GSI/SOP/BS/RA/C/6 – Procedure for Analyzing Total Residual Chlorine (TRC) Concentrations in Water*
- *GSI/SOP/BS/RA/C/8 – Procedure for Analyzing Total Suspended Solids (TSS)*

AUDIT QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
1. Describe the analytical instrumentation. List the brand and model number for each instrument.				
2. Are calibration and maintenance logs kept for the instrumentation (e.g., balances and other equipment)?				
3. Review the maintenance and operational records for the equipment. Based on your findings, do all instruments/equipment appear to be in good operating condition?				
4. Are the manufacturer's operating manuals readily available to the instrumentation operators?				
5. Describe the routine calibration procedure.				
6. Does the calibration documentation show that the calibration procedures are being followed?				
7. Do the calibration standards have the appropriate levels (i.e., bracket the samples to be measured)?				
8. What is the instrumentation calibration error according to the calibration documentation?				
9. Are duplicate samples collected and analyses conducted on at least 10% of the physical/chemical samples?				
10. Are reagent blank samples analyzed with each set of samples?				
11. Are a minimum of three and preferably more standards required for standard curves?				
12. When applicable, do routine procedures that require standard curves bracket concentrations?				
13. When applicable, have analytical method detection limits been established and clearly documented?				
Additional Questions or Comments:				

Initial/Date

ICMP/10-26-09

MICROBIOLOGY KMP Reviewed Datasheets 23 October 2009 and 26 October 2009.

Relevant GSI SOPs:

- *GSI/SOP/BS/RA/MA/1 – Procedure for Quantifying Heterotrophic Plate Counts (HPCs) using IDEXX's SimPlate® for HPC Method*
- *GSI/SOP/BS/RA/MA/3 - Procedure for the Detection and Enumeration of Enterococcus using Enterolert™*
- *GSI/SOP/BS/RA/MA/4 – Procedure for the Detection and Enumeration of Total Coliforms and E. coli using IDEXX's Colilert®*

AUDIT QUESTIONS	RESPONSE Y	N	NA	COMMENTS
1. Are duplicate sample analyses conducted on at least 10% of the microbiology samples?		✓		Duplicates done on fill, not on discharge.
2. Are at least 10% of the samples counted by a second qualified individual (i.e., QA count)?	✓			No QA count for E. coli, Ent, or T.C. QA count for HPC.
3. Are ~~reagent~~ blank samples analyzed with each set of samples? (26) KMP 26 Oct. 09	✓			
4. When applicable, have analytical method detection limits been established and clearly documented?	✓			
Additional Questions or Comments: Control discharge samples 10:43-10:44 collected, time of reciept in lab not recorded. Treatment discharge samples collected ~12:45pm, time of reciept in lab not recorded. Unless control and treatment samples neutralized/analyzed at the same time, there is no data recorded for control samples. TJJ proofed data entry 05 Oct. 2009. KMP verified 10% discharge sample calculations 26 Oct. 2009.				

PHYTOPLANKTON

Relevant GSI SOPs: Reviewed datasheets 19 October 2009. KMP

- *GSI/SOP/LB/RA/SA/1 – Procedure for Algae/Small Protozoan Sample Analysis*

AUDIT QUESTIONS	RESPONSE Y	N	NA	COMMENTS
1. Were all data, observations, and comments appropriately recorded on the "Ballast Water Plankton Count Sheet"?	✓			Time of control analysis must be an error. Sample not collected until 10:43am.
2. Was sample assessment conducted within ~1-1.5 hours after sample collection?	Cannot be determined from datasheet.			
3. Were at least 10% of the samples counted by a second analyst (i.e., QA count)?		✓		No QA count done on Trial 1.

Initial/Date

KMP/26 Oct. 09

Additional Questions or Comments:
"Conc. sample vol." not recorded on treatment tank sample, assuming the sample was concentrated

ZOOPLANKTON

Relevant GSI SOPs:

- *GSI/SOP/BS/RA/C/2 – Procedure for Zooplankton Sample Analysis*

AUDIT QUESTIONS	RESPONSE Y	N	NA	COMMENTS
1. Were all data, observations, and comments appropriately recorded on the "Zooplankton Identification Worksheet"?	✓	"But see Comments"		Data missing Tub 4 data sheet – time completed, initials, temp. Time completed missing tub 5.
2. Was sample assessment conducted within ~2 hours after sample collection?	✓			Started control at "11:10 am, done at ~12:44.
3. Were at least 10% of the samples counted by a second analyst (i.e., QA count)?	✓			QA count was done on control fill for trial #1.

Additional Questions or Comments:
Zooplankton analysis will be done on one tub only instead of pooling 2 tubs and splitting them. Analysis will be conducted on Tub 5 and Tub 4 will be archived.
Subsamples 1 and 2 (rotifer) had greater than 450 total organisms per slide, this is an SOP deviation as no more than ~200 organisms should be present in a 1-mL subsample.

WHOLE EFFLUENT TOXICITY (WET)/COLD WATER BIOASSAY (CWB) TESTING

Relevant GSI SOPs:

- *GSI/SOP/BS/RA/RT/6 – Procedure for Assessing Chronic Residual Toxicity of a Ballast Treatment System to Ceriodaphnia dubia*
- *GSI/SOP/BS/RA/RT/7 – Procedure for Assessing Chronic Residual Toxicity of a Ballast Treatment System to the Fathead Minnow (Pimephales promelas)*
- *GSI/SOP/BS/RA/RT/8 – Procedure for Assessing Chronic Residual Toxicity of a Ballast Water Treatment System to the Green Alga (Selenastrum capricornutum)* DRAFT

AUDIT QUESTIONS	RESPONSE Y	N	NA	COMMENTS
1. Were all data, observations, and comments appropriately recorded on pre-printed data sheets	✓	See comments →		No initials under "Prepared By" column in Stock Solution datasheets.

P. promelas Day 4 datasheet only partially filled out. Initial/Date KMP/10-26-09

and/or laboratory notebooks?				
2. Were all relevant standard operating procedures followed (see above)?	✓ Deviations noted below.			
3. Was an organism QA count done on at least 10% of the test chambers by a second, qualified analyst?	✓ except algal WET test.			no. young C. dubia not verified on Day 3. No QA count for algal WET test.

Additional Questions or Comments:

Christine Polkinghorne transported ~38 L whole effluent collected from Tuble at ~12:30 pm.

SOP deviations: ① C. dubia were fed half the required amount of YCT and algae as directed in GSI/SOP/BS/RA/RT/16.

② C. dubia test set up from 2:39 - 3:10 pm. Day 1 renewal from 9:18-9:34 am. This is less time than directed in the SOP. Organisms exposed to Day 0 water for ~19 hours.

Additional Questions and Comments on Technical Systems Audit:

Control Drain started at 9:46 am.

Treatment Drain started at 11:30 am.

S. capricornutum WET test: On test day 2 MT noted that clumps of algae began to form in the test chambers. On test day 3 MT noted that many of the flasks were "milky white." This may be evidence of bacterial contamination. The test results did not pass the QA/QC parameters specified in GSI/SOP/BS/RA/RT/8 (Draft). This WET test is invalid.

SOP Deviations P. promelas WET test: ① Day 0, organisms added to test chambers from 2:00 – 2:29 pm. Day 1, renewal from 10:13 – 11:19 pm. There were ~20 hours between day 0 and 1 renewal, which is less than 24 +/- 2 hours specified in SOP: GSI/SOP/BS/RA/RT/7.

② Fatheads were fed three times on test renewal day 3, instead of two times as specified in the SOP.

Fathead test termination: 0% - Rep. 3 has 16 surviving larvae but days 0-6 there was 15 larvae in that chamber.

Initial/Date

ICLP/10-2-09